

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020898

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: May 20, 1998
FROM: Steve McCort
SUBJECT: Environmental Assessment

TO: File for NDA 20-898

category
The firm requested a *category* exclusion under 62 FR 145, section 25.31(b) based upon the amount of waste entering the environment will be less than 1 ppb (see Volume 1.3, page 176 of submission for NDA 20-898). The chemistry team leader, Dr. Duu-Gong Wu, in his review of the NDA deemed the Environmental Impact Report satisfactory.

/S/
Stephen McCort
Project Manager, HFD-510

/S/
Duu-Gong Wu, Ph.D.
Chemistry Team Leader
ONDC II, HFD-510

APPEARS THIS WAY
ON ORIGINAL

cc:

NDA 20-898
HFD-510/Division Files
HFD-510/DWu
HFD-510/CSO/McCort